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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED AUG 0 7 2006

Application Number: 09/600,732

Filing Date: July 20, 2000 Appellant(s): SMITS ET AL. **GROUP 1600**

Norman P. Soloway

<u>For Appellant</u>

EXAMINER'S ANSWER

- 1. This is in response to the appeal brief filed 6/12/06 appealing from the Office action mailed on 1/10/06.
 - (2) Related Appeals and Interferences

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The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,613,377	Yamazaki et al.	9-1986
5 660872	Van Loo et al	8-1997

Van Den Ende et al. Fructan synthesizing and degrading activities in chicory roots (Cichorium intybus L.) during field-growth, storage and forcing, Plant Physiology, Vol. 149, (1996), pp. 43-50.

Institut Royal Meteorologique de Belgique. Temparature data. pages 1-2, 1994.

(9) Grounds of Rejection

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The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claim 65-70, 72-78, and 89-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (USPN. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996) and (Institut Royal Meteorologique de Belgique, temperatures for January 1, through December 31, 1994).

Yamazaki et al. teach a method as in claim 65, for improvement of processing of chicory inulin from chicory roots through conventional manufacturing techniques, wherein Yamazaki et al. disclose that the source material for the process are tubers of Jerusalem artichoke (see column

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11, lines 62-66); grown in appropriate regions under proper climatological temperature (grows well in colder conditions, even in waste lands) (see column 12, lines 3-9).

With regard to claim 66-70, Yamazaki et al. also discloses that the inulin could also be derived in similar fashion and could be efficiently produced and harvested in late October and ideally should be processed within a few months (see column 12, lines 21-27);

With regard to claims 73-78, Yamazaki et al. disclose improvement obtaining partial or substantially complete hydrolysis product of inulin (see column 11, lines 62-66); the method of extracting inulin (40%-70% by weight) further comprises extraction with hot water and refining inulin by filtering and cation-exchange (see column 11, lines 1-49);

With regard to claims 89-97, Yamazaki et al. disclose production of fructooligosaccharides from inulin (see column 10, lines 36-56); fructooligosaccharides containing about 0-100% by weight of monosaccharides (see column 10, lines 51-56).

However, Yamazaki did not teach the periods of seeding/growing/processing under climatological temperature conditions, wherein the growing period in northern hemisphere selected from the periods ranging from December 1 till March 14, from March 15 till May 14, from May 15 till May 31, from June 1 till June 14, and from June 15 till November 30, provided that when said chicory has been seeded in the periods from May 15 till May 31, and from June 1 till June 14, the chicory roots have had a growing period of at least 180 days, and provided that when said chicory has been seeded in the period from March 15 till May 14, and in southern hemisphere within a period selected from the periods ranging from June 1 till September 14, from September 15 till September 30, from October 1 till November 14, from November 15 till November 30, and from December 1 till May 31, which are such that during a period of at least

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from the beginning of the third month of the growing period till the end of the processing of the chicory roots the fructan exohydrolase (FEH) gene in chicory roots, has not been triggered by the occurrence of low temperature conditions which are such that the temperature in a thermometer shelter not have dropped below minus 1° C.

Van Den Ende et al. teach a process of claims 65-70, 72-78, 89-97, for synthesizing fructan (inulin) from chicory roots wherein Van Den Ende et al. disclose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, July 26th to November 3rd, October 4th to October 25th, September 13th to December 6th (the period from June 1st to December 6th is 189 days, which is more than 180 days, see page 44, column 1, paragraph 4); (iii) chicory roots stored at +1⁰ C and analyzed at regular intervals (at least once a week) (see page 44, column 1, paragraphs 1 and 4) and (iii) inulin was obtained with a standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (page 45, column 1, paragraph 3). Van Den Ende et al. also disclose changes in the activities of FET during growth, storage and forcing and suggests that cold storage results in a rapid depolymerization of large fructans with a simultaneous increase in smaller fructans, sucrose and fructose (see page 47, col. 1, paragraph 2, page 48, col. 2, paragraph 4).

Further the meteorological data from the Royal Institute of Meteorological center,
Belgium provides support for the temperatures during March 1, 1994 through December 31,
1994, which indicates that the temperatures never dropped below minus 1⁰ C, except for two

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days in December, 1994 (see the chart for temperatures for 1994, wherein December 15 and 16 of 1994 had temperatures below minus 1°C, these two days are out of the growing and processing period of Van Den Ende et al., wherein their growing and processing period ended on December 6th, 1994).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify the process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the optimization of the process of growing and harvesting chicory roots as taught by Van Den Ende et al. and the temperature conditions disclosed by the Royal Institute of Meteorological center, Belgium to achieve expected advantage of developing an improved process for manufacturing chicory inulin from chicory roots under proper climatological temperatures because Van Den Ende et al. states that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). Van Den Ende et al. also taught changes in the activities of FET during growth, storage and forcing and suggests that cold storage results in a rapid depolymerization of large fructans with a simultaneous increase in smaller fructans, sucrose and fructose (see page 47, col. 1, paragraph 2, page 48, col. 2, paragraph 4). Therefore the effect of low temperatures on inulin degradation is a limiting parameter, which is obvious, and known from the prior art cited. Further the meteorological data shows that the temperatures

never were below minus 1⁰ C except for two days in December, 1994). An ordinary practitioner would have reasonable expectation that the combination the method of Yamazaki et al. by incorporating the proper climatological conditions, (that is avoiding no frost days) which partially or wholly fall outside conventional seeding and growing conditions taught by Van Den Ende et al. and the Royal Institute of Meteorological data center, would result in achieving the expected advantage of developing an improved process of preparing chicory inulin. Thus the effect of limiting parameter (low or frost temperatures on FET activity) is known at the time the invention was made and it is prima facie obvious to avoid such conditions in the cultivation of chicory roots. Thus it is prima facie obvious to optimize the cultivating conditions not to fall in the low temperature conditions, and such modification of the method is considered obvious in the absence of secondary considerations.

B. Claims 79-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. (USPN. 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149: 43-50, 1996) and The Royal Institute of Meteorological Center, Belgium, 1994 as applied to claims 65-78, 89-97 above, and further in view of Van Loo (USPN. 5,660,872).

Yamazaki et al. teach a method for processing of chicory inulin from chicory roots through conventional manufacturing techniques, wherein Yamazaki et al. disclose that the source material for the process are tubers of Jerusalem artichoke (see column 11, lines 62-66); grown in appropriate regions under proper climatological temperature (grows well in colder conditions, even in waste lands) (see column 12, lines 3-9). Yamazaki et al. also discloses that the inulin could also be derived in similar fashion and could be efficiently produced and harvested in late October and ideally should be processed within a few months (see column 12, lines 21-27);

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obtaining partial or substantially complete hydrolysis product of inulin (see column 11, lines 62-66); the method of extracting inulin (40%-70% by weight) further comprises extraction with hot water and refining inulin by filtering and cation-exchange (see column 11, lines 1-49); production of fructo-oligosaccharides from inulin (see column 10, lines 36-56); fructooligosaccharides containing about 0-100% by weight of mono saccharides (see column 10, lines 51-56).

Van Den Ende et al. teach a process for synthesizing fructan (inulin) from chicory roots wherein Van Den Ende et al. disclose that (i) the source material for the process are roots of chicory grown in appropriate regions and processed under proper climatological temperature which has not triggered fructan exohydroxylase (FEH) in chicory roots (see page 44, column 1, paragraphs 1-4, page 47, column 1, paragraph 2); (ii) chicory roots were grown for a period of at least 150 days- 180 days and the period selected from periods ranging from June 1, July 26th to November 3rd, October 4th to October 25th, September 13th to December 6th (see page 44, column 1, paragraph 4); (iii) chicory roots stored at +1^o C and analyzed at regular intervals (at least once a week) (see page 44, column 1, paragraph 4) and (iii) inulin was obtained with a standard grade chicory insulin with degree of polymerization (DP) ranging from 6-13 (page 45, column 1, paragraphs 1-4).

However, neither Yamazaki et al. nor Van Den Ende et al. teach the production of inulin free of monomeric saccharides, dimeric saccharides and oligofructose.

Van Loo et al. teach a method for producing inulin free with low molecular weight polysaccharides (sugars) wherein Van Loo et al. disclose that the method comprises isolation of inulin from chicory roots with hot water to obtain aqueous solution of inulin, purification of

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inulin followed by concentrating the inulin solution by partial removal of water (see column 11, lines 47-62); the method also comprises obtaining inulin free of mono-and disaccharides, drying inulin to a particulate form (see column 12, lines 1-67, column 13, lines 1-17). Van Loo et al. further discloses obtaining inulin free of low molecular weight polysaccharides with DP greater than 5 (column 5, lines 5-44).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to modify a process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the method of growing and harvesting chicory roots as taught by Van Den Ende et al. and the method of producing polydispersed saccharides as taught by Van Loo et al. to achieve expected advantage of developing a process for manufacturing improved Grade chicory inulin from chicory roots under proper climatological temperatures and because Van Den Ende et al. taught that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). Further, Van Loo et al. taught that "the degree of polymerization (DP) has direct effect on the solubility of inulin and varies according to the conditions of harvesting chicory roots and saccharides comprise a DP greater than 2 would result in coloration, difficulty in solubility and crystallize at temperatures below 65° C" (see column 1, lines 55-67, column 2, lines 1-22). An ordinary practitioner would have been motivated to modify the method of Yamazaki et al. by

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incorporating the proper climatological conditions and production of inulin free of polydispersed saccharides as taught by Van Den Ende et al. and Royal Meteorological data center and further in view of Loo et al. in order to achieve the expected advantage of developing a method for production of improved grade inulin.

(10) Response to Argument

Prima Facie Case

The prima facie case of obviousness is based upon three references, Yamazaki et al. (US 4,613,377) in view of Van Den Ende et al. (Plant Physiol. Vol. 149, pp. 43-50, 1996) and The Institute Royal Metereologique de Belgique (temperatures for January 1, through December 31, 1994). In the earlier BPAI reversal decision (earlier appeal No. 2004-1498) the Board decision indicated that the examiner offers no evidence to support for optimization conditions of the conventional chicory inulin growing process and no evidentiary support to show that the prior art, Van den Ende et al., performed the study during the time period at which the temperatures never dropped below minus 1° C in Heverlee, Belgium. To address the issue of the temperature, the Examiner reopened the case providing meteorological data from The Royal Institute of Meteorologique Center, Belgium for the year 1994, during which time Van Den Ende et al. performed their study. Examiner also requested the Appellants to provide the information under 37 CFR 1.105 as follows:

Several pieces of information are relevant to the examination of this application. First, does Applicant have separate temperature information for Heverlee, Belgium, for the period of June 1, 1994 to December 9, 1994. Second, does Applicant have evidence regarding triggering of the fructan exohydrolase gene by low temperature during the growth period of chicory. That

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is, was the temperature low enough to trigger this gene or not? Third, did the temperature during chicory's growth conditions ever drop below –1 degree Celsius? Fourth, is Applicant aware of the longest period of cultivation of the chicory by Van den Ende? It appears to be 189 days, is this correct?

With regard to the Examiner's request to provide information, Applicants stated that they were not able to obtain temperature information for Hervelee, but that they were able to obtain temperature information for the period June 1 to December 9, 1994 for a neighboring town of Herent. Examiner requested the information on temperature data for the period for which VDE et al. had performed their study; because Examiner noted that the prior art (VDE et al.) was published in 1996 by the inventors of the instant application. Thus it is reasonable to request the Appellants to show the temperature data for the year 1994, for which period they performed the study.

On page 13 of the appeal brief Appellants argue that the rejection should be reversed as a matter of law since essentially the same art and identical claims were already considered by the Board in the earlier Appeal No. 2004-1498. Appellants also argue that all the four references including the RMI

Appellants' assertions are not proper because the examiner provided the temperature data from RMI after the earlier BPAI decision. As stated above the case was reopened providing the missing temperature data as suggested by the Board.

Temperature below 1° C:

On page 16 of the brief, Appellants assert that the Examiner made same arguments during the earlier Appeal No. 2004-1498 with added incorporation of the RMI data.

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On page 16-21, Appellants assert that Yamazaki et al. does not teach source material rather teaches inulin solution derived from tubers of chicory roots, and does not teach cultivation, growing period of the source material and VDE et al. reference does not relate to cultivation of chicory roots as source material for production of inulin and VDE et al. does not suggest the Appellants' finding that low temperature conditions trigger the FEH and growing chicory outside the conventional processes, and therefore the combination of Yamazaki et al. in view of VDE et al. and Royal Institute Report would not make the instant invention obvious, particularly in view of the temperature data provided by Appellants for Herent. In response to the assertions, Examiner notes that Yamazaki et al. does teach source material as chicory inulin and how to purify inulin to reduce the depolymerization (DP) values and as discussed in the above rejection it would have been obvious to modify the process for processing chicory roots for manufacturing inulin as taught by Yamazaki et al. with the optimization of the process of growing and harvesting chicory roots as taught by Van Den Ende et al. and the temperature conditions disclosed by the Royal Institute of Meteorological center, Belgium to achieve expected advantage of developing an improved process for manufacturing chicory inulin from chicory roots under proper climatological temperatures because Van Den Ende et al. states that "seasonal changes in the biochemistry of fructan storing organs has been largely focused on the examination of changes in the stored carbohydrates. The observed changes in carbohydrate concentrations five-fold increase in fructose concentration) very well correlate with a breakdown of high DP fructans. The shift from high DP fructans from low DP fructans could be due to the action of FFT using low molecular weight carbohydrates as acceptors (see page 47, column 2, paragraph 2, and page 48, column 2, paragraph 2). Van Den Ende et al. also taught changes in

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the activities of FET during growth, storage and forcing and suggests that cold storage results in a rapid depolymerization of large fructans with a simultaneous increase in smaller fructans, sucrose and fructose (see page 47, col. 1, paragraph 2, page 48, col. 2, paragraph 4). Therefore the effect of low temperatures on inulin degradation is a limiting parameter, which is obvious, and known from the prior art cited. As discussed above the newly submitted evidence for the temperatures at Herent for 1994 do not support the equivalent to the temperature data for Heverlee.

With regard to the information on temperature data, Appellants stated that they were not able to obtain temperature information for Hervelee, but that they were able to obtain temperature information for the period June 1 to December 9, 1994 for a neighboring town of Herent and argued that Herent is much closer than Ukkel for which Examiner has provided temperature data for 1994. Appellants show meterological data for yet another region in Brussels, that is Herent, Belgium and assert that they have not been able to obtain temperature information for Heverlee. Based on the daily temperature data from Herent Appellants assert that daily minimum temperature at Herent may be up to about 1° C, and since Herent is closer to Heverlee (about 3 to 4 km) than Ukkel (about 14 km) the minimum temperature at Herent thus logically at Heverlee as well, did drop below -1° C, namely on October 18 (-1.1° C), December 2 (-1.3° C), and December 3 (-1.2° C), and argue that it is reasonable to conclude without reasonable doubt that during the growth period of the chicory roots according to Van Den Ende et al. (VDE), the temperature would have dropped below -1° C not only in December at the end of the growing period, but also by mid-October. The temperature for Ukkel on October 18 was 10 C, and December 2 and 3 it was 0° C which do not deviate significantly from the temperature at

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Herent on those days. Examiner requested the information on temperature data for the period for which VDE et al. had performed their study; because Examiner noted that the prior art (VDE et al.) was published in 1996 by the inventors of the instant application. Thus it is reasonable to request the Appellants to show the temperature data for the year 1994, for which period they performed the study. With regard to the Examiner's request to show the evidence for triggering FEH gene by low temperature, Appellants assert that based on the temperature data provided for Herent, FEH gene had indeed triggered and is confirmed by VDE because the temperature data supports that FEH is triggered after October 15 and indicates the data shows drop in temperature below -1^{0} C on October 18 at Herent. However, the new data on temperature for Herent on October 18 is relatively closer to the temperature data provided by the Examiner for Ukkel on that day. Thus unless Appellants show the temperature data for 1994 at Heverlee, it is not evident that the temperature at Herent is reasonably similar or equal to the temperature for 1994 at Heverlee, for which period the study was performed by VDE et al. Further, as discussed in the above rejection, Van Den Ende et al. explicitly taught changes in the activities of FET during growth, storage and forcing and suggests that cold storage results in a rapid depolymerization of large fructans with a simultaneous increase in smaller fructans, sucrose and fructose (see page 47, col. 1, paragraph 2, page 48, col. 2, paragraph 4). Therefore the effect of low temperatures on inulin degradation is a limiting parameter, which is obvious, and known from the prior art cited. Further the meteorological data shows that the temperatures never were below minus 1⁰ C except for two days in December 15 and 16th, 1994). An ordinary practitioner would have reasonable expectation that the combination the method of Yamazaki et al. by incorporating the proper climatological conditions, (that is avoiding frost days) which partially or wholly fall outside

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Institute of Meteorological data center, would result in achieving the expected advantage of developing an improved process of preparing chicory inulin. Thus the effect of limiting parameter (low or frost temperatures on FET activity) is known at the time the invention was made and it is prima facie obvious to avoid such conditions in the cultivation of chicory roots. Thus it is prima facie obvious to optimize the cultivating conditions not to fall in the low temperature conditions, and such modification of the method is considered obvious in the absence of secondary considerations.

On page 22-23 of the brief, Appellants assert that the rejection under 35 USC 103(a) over Yamazaki et al. in view of the Institute Report and further in view of Van Loo, do not make up the deficiencies of the combination of Yamazaki et al. in view of VDE and Institute Report are not supplied by Van Loo teachings and thus it is not obvious to combine the teachings. As discussed above the combination of Yamazaki et al. in view of VDE and Institute Report does teach the instant invention and as discussed in the above rejection it is obvious to modify the method of Yamazaki et al. by incorporating the proper climatological conditions and production of inulin free of polydispersed saccharides as taught by Van Den Ende et al. and Royal Meteorological data center and further in view of Loo et al. in order to achieve the expected advantage of developing a method for production of improved grade inulin.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

Suryaprabha Chunduru

Primary Examiner

Prabha Chemdury SURYAPRABHA CHUNDURU 8/2/06

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